REMARKS/ARGUMENTS

The non-final office action mailed on December 22, 2010, has been reviewed and carefully considered. Reconsideration is respectfully requested.

In the claims, please amend claim 48 to change the "0" to "O". This is a typographical error. Please amend claims 58, 64 and 66 as well for clarity. No new matter has been added. The amendments to the claims can be viewed in the Amendements section in the Lising of claims beginning on page 2 of this paper.

Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 112, first paragraph for not being enabling. The Applicant respectfully disagrees. The Applicant submits that contrary to the Examiner's assertion, prevention is not regarded in the art as meaning 100% effective. The Applicant provides, after the last page of this paper, a definition for "disease prevention". This reference shows that it is well understood in the art that "prevention" in this sense includes measures not only to prevent the occurrence of a disease, such as reducing risk factors, but also to arrest its progress and reduce its consequences once established. In fact, prevention is even broken down to primary, secondary and tertiary preventions. The specification on page 17 provides that "the compounds of the present invention can be used...to prevent the risk or onset of a given disease." Therefore, the Applicant submits that the Examiner is wrong. That a person of skill in the art would understand from the disclosure that "preventing the risk or onset" does not mean that it necessarily is 100% effective. The term "prevention" is thus a relative term, and means that the probability of obtaining a disease is reduced, or that the onset of such a disease is postponed.

The present invention relates to a combination of two "compounds", i.e. a plant or fish oil (indicated by (1) in claim 48), and lipid compound (indicated by (2) in claim 48). The Examiner appears to be indicating that the compounds of (2) are prodrugs of the fatty acid TTA. This is not correct.

TTA is one of the compounds covered by the definition of (2). The definition also

covers other fatty acids as defined by the formula in (2a), and also more complex lipid compounds as defined by the definition in (2b) and (2c).

TTA has however been used as a test compound (representing a compound of (2)) for establishing of the biological effects of the present inventive combination, i.e. the combination of (1) and (2).

The skilled person based on the experiment provided in the application for the combination of TTA and an oil, and with the knowledge available prior to the filing of the present application would have expected that also the other compounds defined by claim 48 will have similar effects. This assumption is based on the following:

a) all compounds of claim 48 contains a modified fatty acid analogue, either present as a fatty acid per se, or incorporated in a more complex lipid, such as the lipids indicated by the formulas (I) and (II). This modified fatty acid entity is characterized by either of the definitions 2a, 2b(iii) or 2c(iii);

b) The inventor of the present invention has filed several patent applications on such modified fatty acids (similar to the one defined by the (2a) (such as for instance the cited publication WO99/58121), and also for more complex lipids with such a modified fatty acid incorporated, (such as WO2004/000854);

c) All previous experimental results have shown that TTA is a representative example for the fatty acids defined by (2a), and that also other fatty acids within this definition behave similar to TTA;

d) Previous experimental results for the complex lipids show that the causative entity for the biological effects is the modified fatty acid that is incorporated the lipid, for instance TTA incorporated in a phosphatidylcholine (PC) molecule;

e) The skilled person will thus expect that all compounds defined by the formulas of the claims will have the same qualitative effect as TTA;

f) The specification contains a detailed elaboration of how the fatty acids and complex lipids can vary;

g) The present invention relates to a combination of such a fatty acid or complex

lipid (indicated by the component (2) in the claims) and plant or fish oil (indicated as component (1));

h) The experimental section contains a description of some general experimental results obtained for the present invention, for instance an effect on phospholipids, cholesterol and triacylglycerol. These results are qualitatively similar to the results obtained by the fatty acid or complex lipid alone, i.e. without the addition of the protein (1). However, the effects are synergistically and/or additively improved by the addition of the oil (1) (which is the argument for inventiveness); and

i) The skilled person will (based on (h)) expect that the combination of (2) fatty acid/complex lipid and (1) fish or plant oil also will give an improved effect (compared to fatty acid/lipid complex alone) for other diseases that the fatty acid/lipid complex are known to have an effect.

It is thus our opinion that the claims are sufficiently supported by the fact that;

i) TTA (as shown in previous patent applications by the inventor) is a representative example for all the compounds defined in the claims, and

ii) only diseases for which there is a known effect of TTA are claimed.

Further, the Applicant requests that the Examiner recognize this particular invention has been granted as a patent in Russia and New Zealand, and these patent offices have not objected to the sufficiency of the disclosure. Furthermore, a similar application claiming a combination of a protein and the compounds of (2) has been accepted in USA as US 7,659,242.

Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 112, second paragraph for being indefinite. The claims have been amended and the applicant submits that the amendments overcome the rejection thereof. The Applicant has amended the claims to provide R'-X-$(CH_2)_{2n+1}$-COO-R" for clarity. Furthermore, regarding the markush groups, the term "comprising" has been amended to "consisting of". Moreover, the Applicant has amended the claims to remove "a CH2 group".

Claims 64 and 66 were also rejected as being indefinite but the Applicant has removed the narrower ranges. The term "animal" has also been amended to read "non-human animals".

The Applicant submits that these amendments and remarks overcome the rejection and requests withdrawal thereof.

Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. §102(b) as being anticipated by Berge (U.S. 6,365,628). The Applicant respectfully disagrees and submits that the claims are novel and not anticipated thereby. These same claims are rejected under 35 U.S.C. §103(a) as being obvious over Berge et al. (Current Opinion in Lipidology, 2022), Madsen et al. (journal of Lipid research, 2002), and Slorve et al. (Biochimie, 2005) in view of Aude et al. (Current Opinion in Cardiology 2004), Storlien et al. (Science, 1987), Esposito et al. (Journal of the American Medical Association, 2004) and Aguilera et al. (Journal of Nutritional Biochemistry, 2004). The Applicant submits that the claims are also non-obvious and allowable.

Claim 48 has been amended to specifically exclude sunflower oil.

US 6,365,628 does not disclose an improved effect of a combination of non-ß-oxidable compounds and oils. The experiments given in the present application, including the experiments on weight gain (experiment 5), compare rats fed a normal diet (standard chow), a high fat diet, and a high fat diet and TTA. The results show that weight gain (and related parameters) are high, as would be expected, with the high fat diet as compared with the normal diet. The addition of TTA to the high fat diet largely counteracts this weight gain. Thus, the results show that TTA can reduce weight gain caused by a high fat diet, and the use of sunflower oil is incidental. However, as an incidental use may still be novelty destroying, we have modified the claims to exclude sunflower oil.

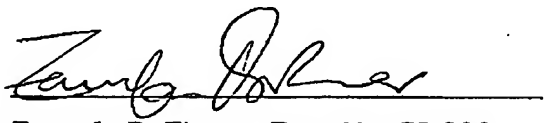
Further, US 6,365,628 does not show that the combination of TTA and oil is especially beneficial, as the present invention does. To do this, one would have to have results for a normal (not high fat) diet with TTA as well, so that the effect of TTA with and without extra fat could be ascertained. This was not done in US 6,365,628, and thus the present application is indeed not taught or suggested by US 6,365,628.

The present invention provides a combination of non-ß-oxidable compounds and oils, which have a surprising synergistic benefit. If the oils and compounds (also being fats) had the same effect one would expect the combination thereof to have a less than additive effect. If the effects were due to entirely separate mechanisms one would expect up to an additive effect. The effects shown in the experimental section are however often larger than an additive effect would have been, so there must be a synergistic effect of combining oil and non-ß-oxidable compounds, and this is indeed surprising, unexpected and inventive. None of the references in whole or in combination disclose the same.

The Applicant submits, therefore, that at least for these reasons, the claims are novel, non-obvious and allowable. Withdrawal of the rejections is respectfully solicited.

Respectfully submitted,

Dated: 6-21-2011



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